Kansas Medical Assistance Program

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

March 09, 2005

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas March 09, 2005	**Members Present:** Michael Burke, M.D., Ph.D., Chair; R. Kevin Bryant, M.D., CMD; Dennis Grauer, Ph.D.; Linda Kroeger, ARNP; John Lowdermilk, R.Ph.; Barry Sarvis, R.Ph.; Brenda Schewe, M.D.; Roger Unruh, D.O. **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Anne Ferguson, R.Ph., DUR Program Director; Erica Miller **EDS Staff Present:** Karen Kluczykowski, R.Ph.; Deb Quintanilla, R.N.	**Representatives:** Chris Johnson, R.Ph. (ACS Heritage), Craig Boon (ACS Heritage), Jeff Knappen (Allergan), Patty Laster (Genentech), Bruce Kirby (Genentech), Brett Marchant (Schering Plough), Brad Hanes (Wyeth), Jon Snow (UCB Pharma), Dave Hanson (Pfizer), Ann Gustafson (GlaxoSmithKline), Patti Wingbermuehle (AstraZeneca), Kent Pearson (Abbott), Stephanie Miller (Amgen), Deron Jones (Wyeth), Shannon Hebert (Pfizer), Elizabeth Stoltz (Janssen), Jack Trupp (Ortho McNeil), Charles Dahm (Amgen), Jim Baumann (Pfizer), Mike Hutfles (Kansas Governmental Consulting), Mike Moratz (Merck), Chris Lepore (Johnson & Johnson)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:45a.m.	
II. Introduction of New DUR Director	• Mary Obley introduced the New DUR Director, Anne Ferguson. • Anne presented information about herself, and then informed the attendees that public comment has been limited to 5 minutes.	
III. Review and Approval of November 10, 2004, Meeting Minutes	• There were no additions or corrections to the November 2004, meeting minutes.	• A motion to approve the minutes as written was made by Dr. Unruh and seconded by Dr. Schewe. The motion carried unanimously by roll call.
IV. New Business **A. Growth Hormones**	• Mary stated that she worked with Dr. Wallace, SRS Medical Director, and with Dr. Dykstra, a Pediatric Endocrinologist from Wichita, to revise the growth hormone criteria. Dr. Dykstra had some concerns with the current growth hormone criteria. Mary then reviewed the draft growth hormone criteria.	

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't	• Dr. Burke reviewed the letters from Children's Mercy Hospital and Kansas University Medical Clinic. The letters stated that they did not approve of the draft criteria for growth hormones, they requested that Idiopathic Short Stature, Small for Gestational Age, and Prader-Willi Syndrome be covered diagnosis. Dr. Burke asked if there is an appeals process for beneficiaries that do not meet the criteria, but the physicians feel they should receive growth hormones. Mary stated that there is. • Dr. Schewe stated that there have been some studies showing patients that are not allowed growth hormones for short stature are more likely to have diabetes. • Dr. Burke stated that he did not feel comfortable approving this prior authorization (PA) when we have letters of objection from pediatric endocrinologist. Dr. Grauer stated that he would like to see growth hormone evidence to support the growth hormones indication. Dr. Burke stated that we could table the growth hormone PA for now and contact Dr. Dykstra and the other pediatric endocrinologist and invite them to the next meeting. We could also request that SRS provide evidence and expenditures regarding growth hormones. • Mary stated that SRS could bring growth hormones back to the next meeting.	
1. Public Comment	• Jim Baumann (Pfizer) presented information to the DUR Board regarding growth hormones. He stated that Idiopathic Short Stature, Small for Gestational Age, and Prader Willi Syndrome are all approved indications by the FDA. • Mary stated that the FDA has approved the use of growth hormones in short stature, but it is a cosmetic use. Medicaid does not cover drugs for cosmetic uses.	
2. DUR Board Recommendations	• With no further discussion, a motion was placed before the board. • Dr. Burke requested that in the future drug manufacturers provide letters of testimony or other support materials to Mary and Anne prior to the scheduled DUR meeting, so that they can be distributed to Board members for consideration.	• A motion was made by Dr. Bryant and seconded by Dr. Unruh to table growth hormones until further evidence is collected. The Board would like expert testimonies from an endocrinologist, evidence for efficacy beyond cosmetic use, how many people are currently receiving growth hormones, other State PA criteria, and how this might affect usage if additional indications are listed. The motion carried unanimously by roll call.

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't	• Mary stated that Medicaid cannot afford to cover this drug for everyone. Karen K asked the pharmaceutical companies if the indigent care program would cover growth hormones if Medicaid doesn't. Jim Baumann (Pfizer) stated that the indigent care program would cover growth hormones, but they avoid covering growth hormones if they know the patients insurance will deny coverage when indigent care coverage stops. Mary stated that she has spoken to a nurse case manager from the Pfizer Bridge Program. Mary asked her if beneficiaries or physicians were given any materials or explanations on how the drug was being offered and what the terms were. The Pfizer nurse case manager told Mary that Pfizer offers the drug at no cost to the patient and that they do not consider a patients insurance or specific criteria, she stated that they worry about insurance and appeals later. Mary then asked what provisions Pfizer might have in place in the case where a beneficiaries' insurance will not cover the drug once they have been started on the free program. The Pfizer nurse case manager answered that Pfizer has a financial aid program available to those patients. Mary stated that she has received multiple appeals regarding patients that were receiving coverage of growth hormones through the indigent care program and then were unhappy when they did not qualify for continued coverage through the Medicaid program.	
B. ACS Heritage **1. Outcome Studies**	• Chris Johnson (ACS Heritage) presented data from the Hyperlipidemia and the Diabetes Outcome targeted interventions. Data suggest improved treatment compliance resulting from the interventions	
2. Updates	• Chris Johnson stated that the next intervention will be Falls in Elderly & Psychiatric Coordination of Care.	
C. Antiepileptics – Appropriate Indications & Diagnosis Codes	• Anne presented information regarding the antiepileptics. She stated that Gabapentin and Topiramate are listed as second and third in the antiepileptics class, for amount paid by Kansas Medicaid. After reviewing the usage and diagnosis, Topiramate had an estimated use of 57% for off label diagnosis and Gabapentin had an estimated use of 43% for off label diagnosis. The State is planning on requiring the pharmacist to enter an ICD-9 code when filling the prescription; the diagnosis has to be one of the FDA approved indications. The DUR Board reviewed	

TOPIC	DISCUSSION	DECISION/ACTION
Antiepileptics – Con't **1. Public Comment**	Possible ICD-9 codes for use with these antiepileptic agents. The need for education of the physicians and pharmacist prior to the changes was discussed. The physician would have to write the indication on the prescription, for example, neuropathic pain and then the pharmacist would enter the ICD-9 code. • Chris Lepore (Johnson & Johnson) presented information to the DUR Board regarding Topiramate. It appears that the utilization of this drug for off label uses is localized to psychiatrists. He has two question for the Board. What happens when the pharmacist receives a prescription that does not have the diagnosis written and the pharmacist can't reach the physician, will the pharmacist still fill the prescription? Second, is there a way to limit this restriction to the psychiatric community only? Anne stated that this should not be anything new to the pharmacist; they currently have to enter a diagnosis code for provigil, pregnancy drugs, and stimulants. Mary stated that we do plan to educate the pharmacist and the physicians prior to the implementation of this change and it is not possible, in the system, to split up who does and doesn't have to enter the diagnosis code. Karen stated that the stimulants used to require a PA and then it was changed to the entering of a diagnosis code; which is a more efficient process. • Ms. Kroeger stated that the unspecified peripheral neuropathy could cover all neuropathic pain diagnosis. • Dr. Lowdermilk stated that this change will require education, for example, mailings to physicians and pharmacists. Dr. Bryant stated that everyone should also learn from experience.	
2. DUR Board Recommendation	• With no further discussion, a motion was placed before the board. • Mr. Sarvis asked what the plan for education currently is. Anne stated that we would start with a pharmacy bulletin and possibly an announcement in the DUR Newsletter. • Dr. Burke and Mr. Sarvis discussed the current process of obtaining a diagnosis when it is not listed on the prescription. Mr. Sarvis stated that the diagnosis have to be written by the physician, so this can be a time consuming process. Mary stated that it will not be required	• A motion was made by Dr. Schewe and seconded by Ms. Kroeger to require pharmacist to enter the ICD-9 code for FDA approved indication for Gabapentin, neuropathic pain and epilepsy, and Topiramate, migraines and epilepsy. The neuropathic pain ICD-9 will be 356.9 for all neuropathy diagnosis.

TOPIC	DISCUSSION	DECISION/ACTION
Antiepileptics – Con't	to have the diagnosis hand written on the prescription by the physician, the pharmacist could get the information over the phone. • Mr. Lowdermilk asked if we will be grandfathering for the patients currently taking Gabapentin or Topiramate for a psychiatric reason. Anne stated that no grandfathering is being planned.	• A roll call vote was taken with Dr. Lowdermilk voting no and the rest voting yes. The motion passed.
D. TB Test – Frequency **Adalimumab (Humira®)** **Etanercept (Enbrel®)** **Infliximab (Remicade®)** **1. Public Comment**	• Mary stated that it was decided to place this on the agenda due to needing some clarification for the PA unit. The PA unit has been asking if the patients need a TB test before they approve the PA renewals or if they only need the TB test prior to the initial PA. SRS is recommending that we require a TB test prior to the initial PA and then it will be at the discretion of the physician after that. • Charles Dahm, PharmD (Amgen) stated that the documentation he found supports the SRS recommendation. • Mr. Sarvis asked for review of the current PA criteria. Mary stated that it doesn't specify the frequency of the TB test, it states TB test required. • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Unruh and seconded by Dr. Grauer to require a TB test prior to the initial PA and then for subsequent PA renewals the TB test will be at the discretion of the physician. The motion carried unanimously by roll call.
E. Discussion/Approval of PDL and Resulting PA Criteria for Non-Preferred Drugs **1. Inhaled Corticosteroids** **a. PDL Advisory Committee Recommendation** **b. SRS Proposal for Preferred Drugs and PA Criteria**	• Dr. Burke stated that the PDL Committee determination was that all formulations of Inhaled Corticosteroids are clinically equivalent. The Committee also suggested that a pediatric formulation be available. • Mary stated that the recommendation from SRS is for Flunisolide (AeroBid®), Beclomethasone Dipropionate (Vanceril®), Fluticasone Propionate (Flovent®, Flovent Rotadisk®), and Budesonide Inhaled Suspension (Pulmicort Respules®) (6 and under only) to be preferred Inhaled Corticosteroids, and PA required for Flunisolide/Menthol (AeroBid M®), Beclomethasone Dipropionate (QVAR®), Triamcinolone Acetonide (Azmacort®), Budesonide Inhalation Powder (Pulmicort	

TOPIC	DISCUSSION	DECISION/ACTION
Inhaled Corticosteroids – Con't	• Turbuhaler®), and Budesonide Inhaled Suspension (Pulmicort Respules®) (7 and over only).	
c. Public Comment	• No public comment.	
d. Discussion	• Ms. Kroeger had some concerns with requiring a PA for Pulmicort Respules® for nursing home patients. Usually when she starts a patient on inhaled corticosteroids, she wants them to start ASAP, it is not logical to have to wait 24 hours before the prescription can be filled. Mary stated that we could make nursing home patients exempt from PA for that drug. • Dr. Burke asked if the drugs are on the shelf in a nursing home. Ms. Kroger stated that it depends on the nursing home, but usually you have to send the prescription to a pharmacy and then they bring it to you. Deb stated that if Ms. Kroger already had the PA forms that she could fill out her portion and then send it to the pharmacist to speed up the process. Deb also pointed out that PAs are approved within 24 hours, but it is usually less time than that. If everything is filled out correctly and it is within business hours the PA can be approved within 5 minutes. • Anne asked if it would be possible to exempt nursing home patients from the PA process on Pulmicort Respules®. Karen said that it would be possible, the system could be set up to allow patients 6 and under and nursing home patients exemption from the PA process on Pulmicort Respules®. • Mary stated that the effective date for the Medicare Modernization Act (MMA) will be January 1, 2006. Therefore, the time and cost to change the system to allow exemption from PA for Pulmicort Respules® for nursing home patients would not be feasible	
e. DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Schewe to accept the SRS recommendation for Flunisolide (AeroBid®), Beclomethasone Dipropionate (Vanceril®), Fluticasone Propionate (Flovent®, Flovent Rotadisk®), and Budesonide Inhaled Suspension (Pulmicort Respules®) (6 and under only) to be the Preferred Inhaled Corticosteroid, and PA required for Flunisolide/Menthol (AeroBid M®), Beclomethasone

TOPIC	DISCUSSION	DECISION/ACTION
Inhaled Corticosteroids – Con't		Dipropionate (QVAR®), Triamcinolone Acetonide (Azmacort®), Budesonide Inhalation Powder (Pulmicort Turbuhaler®), and Budesonide Inhaled Suspension (Pulmicort Respules®) (7 and over only) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
2. Intranasal Corticosteroids **a. PDL Advisory Committee Recommendation**	• Dr. Burke stated that the PDL Committee determination was that all formulations of Intranasal Corticosteroid drugs are clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Fluticasone Propionate (Flonase®) Flunisolide (Nasarel®), and Mometasone Furate Monohydrate (Nasonex®) to be preferred Intranasal Corticosteroids, and PA required for Budesonide (Rhinocort®, Rhinocort AQ®), Beclomethasone Dipropionate (Beconase®, Vancenase®, Beconase AQ®, Vancenase AQ®), Triamcinolone Acetonide (Nasacort®, Nasacort AQ®), and Flunisolide (Bausch and Lomb).	
c. Public Comment	• No public comment.	
d. Discussion	• No Board discussion.	
e. DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Dr. Bryant to accept the SRS recommendation for Fluticasone Propionate (Flonase®) Flunisolide (Nasarel®), and Mometasone Furate Monohydrate (Nasonex®) to be preferred Intranasal Corticosteroids, and PA required for Budesonide (Rhinocort®, Rhinocort AQ®), Beclomethasone Dipropionate (Beconase®, Vancenase®, Beconase AQ®, Vancenase AQ®), Triamcinolone Acetonide (Nasacort®, Nasacort AQ®), and Flunisolide (Bausch and Lomb) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
3. Second Generation Antihistamines **a. PDL Advisory Committee Recommendation**	• Dr. Burke stated that the PDL Committee determination was that all formulations of Second Generation	

TOPIC	DISCUSSION	DECISION/ACTION
Second Generation Antihistamines – Con't	Antihistamines are clinically equivalent. The Committee also recommended that a pediatric formulation be available.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Loratadine – all dosage forms OTC, Loratadine Syrup (Claritin Syrup®), and Loratidine/Pseudoephedrine (KBH only) to be preferred Second Generation Antihistamine drugs, and PA required for Cetirizine – all formulation (Zyrtec®, ZyrtecD®, Zyrtec Syrup®), Fexofenadine (Allegra®, AllegraD®), and Desloratadine (Clarinex®). Mary stated that she spoke with a few pharmacies and the pharmacist stated that they have had numerous patients switching from Zyrtec Syrup® to Claritin Syrup® and they haven't had any problems.	
c. Public Comment	• Jim Baumann (Pfizer) presented information regarding concerns he has with Zyrtec® requiring PA. Most providers are reluctant to go through the PA process, so they will go with whatever drug does not require a PA.	
d. Discussion	• Dr. Burke asked if Mary knew how many patients are currently on Zyrtec Syrup®. Mary stated that she could get the numbers. • Mr. Sarvis asked if clinical equivalence has always been the outcome of this class of drugs at the PDL meetings. Dr. Burke stated that this class of drugs have been reviewed twice and both time the decision was clinical equivalence.	
e. DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Mr. Sarvis to accept the SRS recommendation for Loratadine – all dosage forms OTC, Loratadine Syrup (Claritin Syrup®), and Loratidine/Pseudoephedrine (KBH only) to be preferred Second Generation Antihistamine drugs, and PA required for Cetirizine – all formulation (Zyrtec®, ZyrtecD®, Zyrtec Syrup®), Fexofenadine (Allegra®, AllegraD®), and Desloratadine (Clarinex®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.

TOPIC	DISCUSSION	DECISION/ACTION
4. New Urinary Incontinence Drugs **a. PDL Advisory Committee Recommendation**	• Dr. Burke clarified that the PDL Committee focused its review on the newly release Urinary Incontinence (UI) drugs. Dr. Burke stated that the PDL Committee determination was that all formulations of Urinary Incontinence Drugs are clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Tolterodine LA (Detrol LA®), Oxybutynin (Ditropan®), and Solifenacin Succinate (VESIcare®) to be preferred Urinary Incontinence drugs, and PA required for Flavoxate HCl (Urispas®), Oxybutynin XL (Ditropan XL®), Tolterodine (Detrol®), Oxybutynin Patches (Oxytrol®), Trospium Chloride (Sanctura®).	
c. Public Comment	• No public comment.	
d. Discussion	• No Board discussion.	
e. DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Mr. Sarvis to accept the SRS recommendation for Tolterodine LA (Detrol LA®), Oxybutynin (Ditropan®), and Solifenacin Succinate (VESIcare®) to be preferred Urinary Incontinence drugs, and PA required for Flavoxate HCl (Urispas®), Oxybutynin XL (Ditropan XL®), Tolterodine (Detrol®), Oxybutynin Patches (Oxytrol®), Trospium Chloride (Sanctura®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
5. Oral Bisphosphonates **a. PDL Advisory Committee Recommendation**	• Dr. Burke stated that the PDL Committee determination was that all formulations of Oral Bisphosphonates are clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that there are two drugs in this class, SRS made the decision to place both drugs on the Preferred Drug List, so there is no PA form to approve. Oral Bisphosphonates will be posted on the Preferred Drug List on the website.	
c. Public Comment	• No public comment.	
d. Discussion	• No board discussion	
e. DUR Board Recommendation	• No recommendation needed.	

TOPIC	DISCUSSION	DECISION/ACTION
V. Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Schewe to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 11:45 a.m.